



Winter 2001

CLIA BITS



North Dakota Department of Health
Division of Health Facilities

Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota CLIA program from Jan. 1, 2000, through Dec. 31, 2000.

- ?? The most common deficiency cited in 2000 was D7047, comparison of test results. This requirement states that if a laboratory performs tests that are not included under Subpart I, Proficiency Testing Program, the laboratory must have a system for verifying the accuracy and reliability of its test results twice a year.
- ?? The second most common deficiency cited was D4001, moderate complexity testing. This deficiency is cited when a laboratory fails to follow the manufacturer's instructions for instrument or test system operation and test performance.
- ?? D2015 was the third most commonly cited deficiency. This requirement states that a laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results, for a minimum of two years from the date of the proficiency testing event.

This also includes the attestation statement provided by the proficiency testing program and signed by the analyst and the laboratory director documenting that proficiency testing samples were tested in the same manner as patient specimens.

- ?? Test records, D3037, was the fourth most commonly cited deficiency. This deficiency is cited when a laboratory's record system fails to include the patient identification number, accession number, or other unique identification number.
- ?? And lastly, coming in fifth, was D4300. This requirement states that for non-manual hematology testing systems, excluding coagulation, the laboratory must include two levels of control each eight hours of operation. This is similar to D4302, which states that for all non-manual coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

If you have any questions about the deficiencies or the requirements, please contact the North Dakota Department of Health, Division of Health Facilities, at 701.328.2352.



National Laboratory Training Network

The National Laboratory Training Network is a training system sponsored by the Association of Public Health Laboratories and Centers for Disease Control and Prevention. The NLTN provides laboratory training courses in clinical, environmental and public health laboratory topics. The NLTN offers a variety of laboratory training programs, including a lending library of laboratory education resources and continuing education workshops and seminars. Also available are NLTN Workshops-In-A-Box, self-facilitated laboratory training courses that provide CEUs for just a small fee.

For more information, call 1.800.536.NLTN (6586) or e-mail woffice@nltn.org. The NLTN also has a website that can be found at www.phppo.cdc.gov/dls/nltn.

HCFA Announces Pilot Survey of Waived and Provider Performed Microscopy Laboratories

The Health Care Financing Administration (HCFA) has expanded the pilot project concerning the inspection of waived and provider-performed microscopy (PPM) laboratories. The initial pilot occurred in Colorado and Ohio. The pilot was due to the increase in the types of tests waived, the large number of laboratories with no oversight and the serious findings during complaint investigations of waived laboratories. Significant quality and certification problems were identified in more than 50 percent of the laboratories. The expansion added eight states to the pilot, verifying the scope and seriousness of the original finding. The results will be

evaluated and distributed in early 2001. Following the conclusion of the expanded pilot, HCFA, the CDC and the FDA will evaluate the findings to determine the next steps for the CLIA program.

Take time to work, it is the price of success.
 Take time to think, it is the source of power.
 Take time to play, it is the secret of perpetual youth.
 Take time to read, it is the foundation of wisdom.
 Take time to be friendly, it is the road to happiness.
 Take time to dream, it is hitching your wagon to a star.
 Take time to love and be loved, it is the privilege of the gods.
 Take time to look around, it is too short a day to be selfish.
 Take time to laugh, it is the music of the soul.

--- Old English Prayer



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